
Guidance

The Open Public Hearing FDA Advisory Committee Meetings

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Comments and suggestions may be submitted at anytime for agency consideration to the Division of Dockets Management, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that is published in the *Federal Register*.

For questions regarding this document, contact Linda Ann Sherman at 301-827-1220.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner**

**[Date]
[Category]**

Guidance

The Open Public Hearing

FDA Advisory Committee Meetings

Additional copies are available from:

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**U.S. Department of Health and Human Services
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The Open Public Hearing FDA Advisory Committee Meetings²

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create nor confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The Food and Drug Administration (FDA) encourages participation from all public stakeholders in its decision-making processes. Every advisory committee meeting includes an open public hearing (OPH) session, during which interested persons may present relevant information or views orally or in writing. 21 CFR § 14.25(a). FDA's regulation, 21 CFR § 14.29, requires that a minimum of 60 minutes per meeting be dedicated to an open public hearing session for oral presentations, unless public participation does not last that long. For meetings that extend more than 1 day and/or meetings with multiple topics, the OPH session can be divided into multiple parts. If there is an overwhelming interest by the advisory committee in a specific topic, then the committee chair³ may extend the OPH session.

The time and location of the meeting and the OPH session is published in the *Federal Register* (21 CFR § 14.20) at least 15 days before a meeting.

This guidance is intended to answer questions about how the public may participate at an open public hearing session. This includes, but is not limited to, general members of the public; individuals or spokespersons from the regulated industry (except the sponsor whose product is under review); consumer advocacy groups; or professional organizations, societies or associations.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance has been prepared by the Advisory Committee Oversight and Management Staff, Office of External Relations, Office of the Commissioner, Food and Drug Administration.

² This guidance applies to all FDA advisory committees including the panels of the Medical Devices Advisory Committee.

³ The chair is an experienced committee member appointed to preside at committee meetings and ensure that all rules of order and conduct are maintained during each session. 21 § 14.30.

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II. ORAL PARTICIPATION IN AN FDA ADVISORY COMMITTEE OPEN PUBLIC HEARING

A. Providing a Request to Speak at the OPH:

An interested person who wishes to be assured of the right to make an oral presentation at an advisory committee meeting shall inform FDA orally or in writing before the meeting. 21 CFR § 14.29(b). The interested person shall submit the request to the FDA contact person designated in the Federal Register (FR) notice by the listed deadline date. 21 CFR § 14.29(b). FDA staff makes every effort to accommodate a speaker's request. FDA recommends that the request be submitted by mail, telephone, facsimile, or e-mail. Participation is handled on a first come-first serve basis through the request process.

The interested person should include the following with the request:

- Name of the individual or;
- Name of the group, including, the name of the spokesperson making the presentation, a description of the constituency that the group represents, and a brief mission statement of the group;
- Contact information (mailing address, e-mail address, telephone and fax numbers);

The interested person shall also include the following in the submission:

- A description of the general nature of the presentation, pursuant to 21 CFR § 14.29(b). The submitter can include an outline of the presentation to satisfy this requirement. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to FDA, pursuant to 21 CFR § 14.29(b)(1); See subsection D below.
- Amount of time requested for the presentation, pursuant to 21 CFR § 14.29(b). The allotment time is dependant upon the number of requests. FDA usually allots 5 to 10 minutes per person. However, if a large number of speakers have requested to address the committee, FDA may reduce the time allotment for each speaker pursuant to 21 CFR § 14.29(b)(2) and/or extend the time of the OPH session. In the interest of obtaining as many points of view as possible, FDA may require speakers with similar statements to consolidate their presentations into a single presentation, pursuant to 21 CFR § 14.29(b)(2). In the interest of fairness, all speakers are asked to adhere to their allotted time.

Audio-visual/media equipment is available at advisory committee meetings. FDA asks that the interested person provide a written request for use of the equipment along with an electronic version of the power point presentation or any overheads at least one week in advance of the

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meeting. Please consult with the FDA executive secretary (FDA staff)⁴ on issues related to the compatibility of software/hardware for your presentation.

B. Confirmation to Speak at the OPH

1. FDA staff intends to contact speakers by e-mail, facsimile, or telephone to confirm their participation.
2. FDA intends to assign a time allocation. In the event of scheduling changes and if time permits, FDA staff will contact the speaker concerning these changes.
3. If the speaker is delayed or is unable to attend the meeting, FDA recommends that an FDA representative be contacted. If the speaker would still like to make a presentation and time and resources permit, it may be possible to arrange for an alternative time to speak during the meeting; to have the speaker's statement read by a speaker representative; or to have the statement, or a summary of the speaker's statement, made part of the public record via the public docket. However, once the public hearing portion of the meeting has ended, further oral comments from the public will only be accepted at the discretion of the FDA advisory committee chair.

C. Confirmed Speaker Check-In the Day of the Meeting

1. Check-in is at the registration table. Speakers should introduce themselves to the Executive Secretary and other FDA staff. OPH speakers often have a designated seating area.
2. Please work with the Executive Secretary or other designated FDA staff to facilitate your presentation (e.g., slides) and handout distribution.

D. Handouts for the Day of the Meeting

1. FDA distributes to the advisory committee before or at the meeting those copies of handouts received from public speakers prior to the deadline in the FR notice, pursuant to 21 CFR § 14.29(b)(1).⁵
2. A copy of slide presentations should be given to FDA for posting on the FDA web site at <http://www.fda.gov/oc/advisory/default.htm>.
3. A copy of the written information will be included in the permanent record of the meeting. 21 CFR § 14.60(b)(3).

⁴ The Executive Secretary is the Designated Federal official (DFO) who coordinates the activities of the advisory committee, serves as the link between committee members, FDA, industry and the public.

⁵ FDA plans to issue draft guidance in the future to address the issue of written material submitted after the deadline stated in the Federal Register notice.

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E. Logistics of an Oral Presentation

1. A podium or lapel microphone is available or, alternatively, an audience microphone is located conveniently on the floor.
2. A timer is used to monitor the speaker. If the timer is not used at a particular meeting, the Committee Chair or the Executive Secretary signals the speaker when his or her allotted time has expired.
3. When the oral presentation concludes, FDA recommends that the speaker remain at the podium in case there are questions from the FDA advisory committee.
4. All oral statements are recorded in the transcript of the meeting. Meeting transcripts are posted on the FDA web site approximately three to four weeks after the meeting takes place.

III. FINANCIAL DISCLOSURE

The law requires that the Food and Drug Administration's scientific advisors, who are usually special Government employees (SGEs), disclose potential financial interests or relationships that they may have with the sponsor and/or competitors of the product under discussion at an advisory committee meeting. The financial interests requiring disclosure include stock, grants, consulting, teaching, speaking and writing engagements, expert testimony, patents, and royalties. In addition, the financial interests of a spouse, minor child, and employer are imputed to the committee member.

As noted in this Guidance, at every advisory committee meeting, at least one hour is set aside for an open public hearing. At this time, speakers from the general public may make a presentation to the advisory committee. Advisory committee meetings consist of either particular or general matters for discussion and consideration. Particular matters before an advisory committee relate to a specific regulated product and affect a specific manufacturer and its competing products/manufacturers (e.g., NDA, PMA, PLA/BLA, efficacy supplement for new indication). General matters before an advisory committee do not relate to a specific regulated product but instead relate to scientific findings or regulatory issues that may affect various members of the public and regulated industry.

At the commencement of each OPH session, the Chair of the particular advisory committee meeting reads one of the following statements, addressing the issue of financial disclosure for all open public hearing speakers.

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A. Instructive Statement for Particular Matters Meetings

Both the Food and Drug Administration (FDA) and the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with the sponsor, its product, and if known, its direct competitors. For example, this financial information may include the sponsor's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

B. Instructive Statement for General Matters Meetings

Both the Food and Drug Administration (FDA) and the public believe in a transparent process for information gathering and decision-making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement, to advise the committee of any financial relationship that you may have with any company or group that may be affected by the topic of this meeting. For example, the financial information may include a company's or a group's payment of your travel, lodging, or other expenses in connection with your attendance at the meeting. Likewise, FDA encourages you at the beginning of your statement to advise the committee if you do not have any such financial relationships. If you choose not to address this issue of financial relationships at the beginning of your statement, it will not preclude you from speaking.

After each presentation, the Chair or a committee member may question the person concerning the scientific content of his or her presentation. However, neither the Chair nor any committee member should further question the person regarding any potential financial relationships. If the open public hearing participant's statement contains no information about his or her financial relationships relative to the meeting topic, FDA intends to assume that the participant has made a conscious decision not to disclose this information.

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IV. REFERENCES

- A. FDA Advisory Committee Home Page –**
<http://www.fda.gov/oc/advisory/default.htm>
- B. FDA Advisory Committee Annual Calendar of Meetings –**
<http://www.fda.gov/oc/advisory/accalendar/2004/default.htm>
- C. FDA Advisory Committee Information Line Code Numbers –**
<http://www.fda.gov/ohrms/dockets/ac/listinfo.htm>
- D. CODE OF FEDERAL REGULATIONS (CFR PART 14) –**
http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr14_03.html